UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

CHRISTOPHER A. SHAFER, Plaintiff, v. C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC., Defendants.	Case No. C20-1056RSM ORDER DENYING MOTION TO EXCLUDE OR LIMIT OPINIONS OF ROBERT ALLEN, M.D. AND DENYING MOTIONS FOR LEAVE TO RESPOND

This matter comes before the Court on Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s Motion to Exclude or Otherwise Limit Improper Opinions from Robert Allen, M.D., Dkt. #30, and two Motions from Plaintiff seeking leave to file a late response brief to that Motion, Dkts. #37 and #40.

Plaintiff has failed to demonstrate good cause to extend the time for filing a response brief under Rule 6(b)(1). Plaintiff's counsel states he mis-calendared this deadline due in part to the large number of similar cases he is handling. *See* Dkt. #40 at 4 ("Since Defendants' Daubert Motion was served, counsel for Plaintiff has responded to more than thirty motions for summary judgment and Daubert motions in cases involving Bard in federal courts around the country. In this case, the error was the result of a lapse in counsel's calendaring processes…").

This does not demonstrate excusable neglect or good cause for granting the requested relief, rather it reflects a predictable consequence of taking on too many similar cases. Furthermore, given the proximity to trial, permitting a late response would necessitate reply briefing and likely cause some prejudice to counsel. These Motions will therefore be denied.

The Court will thus rule on the underlying issue based solely on the materials submitted by Defendants. The Court will not interpret Plaintiff's failure to file a timely response as an admission of the merits of Defendants' Motion.

The background facts of this case are adequately summarized by Defendants:

> Plaintiff Christopher A. Shafer was treated with a Bard Recovery inferior vena cava filter ("Recovery Filter")—a prescription medical device placed in his inferior vena cava ("IVC"), the largest vein in the body that returns blood from the lower extremities to the heart—to prevent pulmonary embolism. He brings this product liability action, alleging that Bard is strictly liable for defects in warning and design of the Recovery Filter. In support of his claims, Plaintiff disclosed case-specific expert Dr. Robert Allen, and Bard subsequently deposed Dr. Allen.

DKt. #30 at 1.

Federal Rule of Evidence 702 provides that a witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Under Rule 702, the trial court acts as a gatekeeper and ensures that the proffered scientific testimony meets certain standards of both relevance and reliability before it is admitted. *Daubert v. Merrell Dow Pharm., Inc. ("Daubert I")*, 509 U.S. 579, 590, 113 S. Ct.

2786, 125 L. Ed. 2d 469 (1993). The party proffering expert testimony has the burden of showing the admissibility of the testimony by a preponderance of the evidence. *Daubert I*, 509 U.S. at 592 n.10. "[J]udges are entitled to broad discretion when discharging their gatekeeping function" related to the admission of expert testimony. *United States v. Hankey*, 203 F.3d 1160, 1168 (9th Cir. 2000) (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150-53, 119 S. Ct. 1167, 143 L. Ed. 2d 238 (1999)). The Court considers four factors to determine if expert testimony will assist the trier of fact: "(i) whether the expert is qualified; (ii) whether the subject matter of the testimony is proper for the jury's consideration; (iii) whether the testimony conforms to a generally accepted explanatory theory; and (iv) whether the probative value of the testimony outweighs its prejudicial effect." *Scott v. Ross*, 140 F.3d 1275, 1285-86 (9th Cir. 1998).

As an initial matter, this Court must determine whether the proffered witness is qualified as an expert by "knowledge, skill, experience, training or education." Fed. R. Evid. 702. Because the Rule "contemplates a *broad conception* of expert qualifications," only a "*minimal foundation* of knowledge, skill, and experience" is required. *Hangarter v. Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1015-16 (9th Cir. 2004) (emphasis in original) (quoting *Thomas v. Newton Int'l Enters.*, 42 F.3d 1266, 1269 (9th Cir. 1994)). A "lack of particularized expertise goes to the weight of [the] testimony, not its admissibility." *United States v. Garcia*, 7 F.3d 885, 890 (9th Cir. 1993) (citing *United States v. Little*, 753 F.2d 1420, 1445 (9th Cir. 1984)); *Daubert v. Merrell Dow Pharm., Inc. ("Daubert II")*, 43 F.3d 1311, 1315 (9th Cir. 1995).

The trial court must also ensure that the proffered expert testimony is reliable. Generally, to satisfy Rule 702's reliability requirement, "the party presenting the expert must

show that the expert's findings are based on sound science, and this will require some objective, independent validation of the expert's methodology." *Daubert II*, 43 F.3d at 1316. Toward this end, the Supreme Court in *Daubert I* set forth the following factors for the trial court to consider when assessing the reliability of proffered expert testimony: (1) whether the expert's method, theory, or technique is generally accepted within the relevant scientific community; (2) whether the method, theory, or technique can be (and has been) tested; (3) whether the method, theory, or technique has been subjected to peer review and publication; and (4) the known or potential rate of error of the method, theory, or technique. *Daubert I,* 509 U.S. at 593-94. An expert opinion is reliable if it is based on proper methods and procedures rather than "subjective belief or unsupported speculation." *Id.* at 590. The test for reliability "'is not the correctness of the expert's conclusions but the soundness of his methodology.'" *Stilwell v. Smith & Nephew, Inc.*, 482 F.3d 1187, 1192 (9th Cir. 2007) (quoting *Daubert II*, 43 F.3d at 1318).

Alternative or opposing opinions or tests do not "preclude the admission of the expert's testimony – they go to the *weight*, not the admissibility." *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1231 (9th Cir. 1998). Furthermore, "'[d]isputes as to the strength of [an expert's] credentials, faults in his use of [a particular] methodology, or lack of textual authority for his opinion, go to the weight, not the admissibility, of his testimony.'" *Id.* (quoting *McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1044 (2d Cir. 1995)).

Finally, the Court must ensure that the proffered expert testimony is relevant. As articulated in Rule 702, expert testimony is relevant if it assists the trier of fact in understanding evidence or in determining a fact in issue. *Daubert I*, 509 U.S. at 591. Thus, the party proffering such evidence must demonstrate a valid scientific connection, or "fit," between the evidence and an issue in the case. *Id.* Expert testimony is inadmissible if it concerns factual

issues within the knowledge and experience of ordinary lay people because it would not assist the trier of fact in analyzing the evidence. In the Ninth Circuit, "[t]he general test regarding the admissibility of expert testimony is whether the jury can receive 'appreciable help' from such testimony." *United States v. Gwaltney*, 790 F.2d 1378, 1381 (9th Cir. 1986). Because unreliable and unfairly prejudicial expert witness testimony is not helpful to the trier of fact, the trial court should exclude such evidence. *Jinro Am., Inc. v. Secure Invs., Inc.*, 266 F.3d 993, 1004 (9th Cir. 2001). Likewise, expert testimony that merely tells the jury what result to reach is inadmissible. Fed. R. Evid. 704, Advisory Committee Note (1972); *see, e.g.*, *United States v. Duncan*, 42 F.3d 97, 101 (2d Cir. 1994) ("When an expert undertakes to tell the jury what result to reach, this does not *aid* the jury in making a decision, but rather attempts to substitute the expert's judgment for the jury's.").

After reviewing the submitted materials, the Court finds Dr. Allen qualified to opine on the adequacy of the warnings in the Instructions for Use ("IFU") for the filter in question. Defendants argue this witness "is not a warnings expert," has never written an IFU for a medical device, and has never worked for the FDA. Dkt. #30 at 8. However, Defendants admit he is an experienced radiologist, and "may be qualified to opine about the information physicians expect when making decisions about the use of IVC filters and whether that information was in the Recovery Filter's IFU." *Id*. at 9. Because Rule 702 contemplates a broad conception of expert qualifications, only a minimal foundation of knowledge, skill, and experience" is required. *Hangarter, supra*. The Court's review of the attached exhibits demonstrates this witness has the necessary foundation as to this issue. Furthermore, Defendants are splitting hairs as to the particularized expertise required for an expert to opine on this issue, and a lack of particularized expertise goes to the weight of the testimony, not its

admissibility. Defendants are more than free to attack Dr. Allen's qualifications on cross-examination.

The Court finds Dr. Allen qualified to offer opinions on a possible design defect or whether such a defect caused Plaintiff's injuries. Defendants argue this witness "is not an expert in IVC filter design, and his CV does not establish that he has ever designed an IVC filter." Dkt. #30 at 10. It is not clear to the Court that Dr. Allen intends to testify outside his area of expertise, and he is permitted to testify as to what a doctor would expect from this medical device and how this device interacted with a patient such as he would treat within his practice. He is not qualified to testify as to the engineering of the product. Further disagreement as to this issue can be addressed through objections at trial.

Defendants argue that Dr. Allen's opinions on safer alternative filters suffer from unreliable methodology. As an initial matter, although the Court acts as a gatekeeper here, it will not question whether an allegedly safer alternative filter with a different course of treatment—multiple implant procedures instead of one—was a viable alternative design at the time of implementation. This is venturing too far into the factual weeds. Assuming that Dr. Allen's testimony as to a safer alternative filter has at least some merit, Defendants ask the Court to find that this opinion was not based on reliable methodology because Dr. Allen "relied on his 'own experience and review of the medical literature and Bard's internal documents, along with the reports of Dr. McMeeking and others." Dkt. #30 at 12–13. Defendants point out that Dr. Allen cannot support his opinion with citation to articles published after the filter in question was manufactured. However, Defendants do not adequately explain why Dr. Allen, relying on his own experience, medical literature other than those articles, Defendant's internal documents, and the reports of Dr. McMeeking cannot opine on this issue. Dr. Allen is not

basing his opinion solely on subjective belief or unsupported speculation, and the review of Defendants' internal documents and the reports of Dr. McMeeking appear to be a sound methodology for developing this opinion. This will not serve as a basis to exclude opinion testimony. Defendants are more than free to attack Dr. Allen's opinion on cross-examination.

Finally, the Court disagrees that Dr. Allen has failed to reliably apply a differential diagnosis in concluding that Defendants' filter caused Plaintiff's injury. "A medical opinion on causation that is based on a reliable differential diagnosis is admissible under *Daubert*." *Luttrell v. Novartis Pharms. Corp.*, 894 F. Supp. 2d 1324, 1338 (E.D. Wash. 2012), *aff'd*, 555 F. App'x 710 (9th Cir. 2014). But, to conduct a reliable differential diagnosis, "the expert must explain why alternative hypotheses as to causation are ruled out using scientific methods and procedures." *Id*. Defendants argue, "[i]n his report, Dr. Allen, a medical expert, appears to apply a differential diagnosis to the complications experienced by the subject filter, but not any medical injuries allegedly attributable to the filter…. The next step in the causation chain—connecting any complication experienced by the Recovery Filter to Plaintiff's alleged injuries—is where Dr. Allen… falls short." Dkt. #30 at 15. The Court finds that Dr. Allen's report, submitted by Defendants, adequately explains why alternative hypotheses are ruled out using valid scientific methodology, based on his experience and review of relevant medical records, articles, and reports related to this and related litigation. Defendants' concerns with the weaknesses of Dr. Allen's opinions on causation go to the weight of the testimony, not its admissibility.

Given all of the above, the Court finds no basis to exclude any of Dr. Allen's expert opinions. Having reviewed the above Motions and the remainder of the record, the Court hereby finds and ORDERS:

1) Plaintiffs' Motions seeing leave to file a late response brief to that Motion, Dkts. #37 and #40, are DENIED.

2) Defendants' Motion to Exclude or Otherwise Limit Improper Opinions from Robert Allen, M.D., Dkt. #30, is DENIED.

DATED this 22nd day of September, 2021.

RICARDO S. MARTINEZ
CHIEF UNITED STATES DISTRICT JUDGE